

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning at page 14, line 22, with the following amended paragraph:

In related aspects of the invention, the pharmaceutical composition includes the permeabilizing agent and one or more biologically active agent(s) selected from a small molecule drug, a peptide, a protein, and a vaccine agent. In more detailed aspects, the biologically active agent(s) is/are selected from an opiod, opiod antagonist, corticosterone, anti-inflammatory, androgen, estrogen, progestin, muscle relaxant, vasodilator, antihistamine, histamine receptor site blocking agent, antitussive, antiepileptic, anti-fungal agent, antibacterial agent, cancer therapeutic agent, antioxidant, antiarrhythmic agents, antihypertensive agent, monoclonal or polyclonal antibody, anti-sense oligonucleotide, and/or an RNA, DNA or viral vector comprising a gene encoding a therapeutic peptide or protein. In other detailed aspects, the biologically active agent(s) is/are selected from a therapeutic protein or peptide, for example a protein or active peptide fragment or fusion of tissue plasminogen activator (TPA), epidermal growth factor (EGF), fibroblast growth factor (FGF-acidic or basic), platelet derived growth factor (PDGF), transforming growth factor (TGF-alpha or beta), vasoactive intestinal peptide, tumor necrosis factor (~~TGF~~ TNF), hypothalamic releasing factors, prolactin, thyroid stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), parathyroid hormone (PTH), follicle stimulating hormone (~~FSF~~ FSH), luteinizing hormone releasing hormone (LHRH), endorphins, glucagon, calcitonin, oxytocin, carbetocin, aldoetecone, enkaphalins, somatostin, somatotropin, somatomedin, ~~gonadotrophin~~ gonadotropin, estrogen, progesterone, testosterone, alpha-melanocyte stimulating hormone, non-naturally occurring opiods, lidocaine, ketoprofen, sufentanil, terbutaline, droperidol, scopolamine, gonadorelin, ciclopirox, olamine, buspirone, calcitonin, cromolyn sodium or midazolam, cyclosporin, lisinopril, captopril, delapril, cimetidine, ranitidine, famotidine, superoxide dismutase, asparaginase, arginase, arginine deaminase, adenosine deaminase ribonuclease, trypsin, chemotrypsin, papain, bombesin, substance P, vasopressin, alpha-globulins, transferrin, fibrinogen, beta-lipoproteins, beta-globulins, prothrombin, ceruloplasmin, alpha₂-glycoproteins, alpha₂-globulins, fetuin, alpha-lipoproteins, alpha-globulins, albumin, and/or prealbumin.

Please replace the paragraph beginning at page 58, line 8, with the following amended paragraph:

The instant invention provides novel formulations and coordinate administration methods for enhanced mucosal delivery of biologically active peptides and proteins. Illustrative examples of therapeutic peptides and proteins for use within the invention include, but are not limited to: tissue plasminogen activator (TPA), epidermal growth factor (EGF), fibroblast growth factor (FGF-acidic or basic), platelet derived growth factor (PDGF), transforming growth factor (TGF-alpha or beta), vasoactive intestinal peptide, tumor necrosis factor (~~TGF~~ TNF), hypothalamic releasing factors, prolactin, thyroid stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), parathyroid hormone (PTH), follicle stimulating hormone (~~FSF~~ FSH), luteinizing hormone releasing hormone (LHRH), endorphins, glucagon, calcitonin, oxytocin, carbetocin, aldoetecone, enkaphalins, somatostatin, somatotropin, somatomedin, ~~gonadotrophin~~ gonadotropin, estrogen, progesterone, testosterone, alpha-melanocyte stimulating hormone, non-naturally occurring opioids, lidocaine, ketoprofen, sufentanil, terbutaline, droperidol, scopolamine, gonadorelin, ciclopirox, olamine, buspirone, calcitonin, cromolyn sodium or midazolam, cyclosporin, lisinopril, captopril, delapril, cimetidine, ranitidine, famotidine, superoxide dismutase, asparaginase, arginase, arginine deaminase, adenosine deaminase ribonuclease, trypsin, chemotrypsin, and papain. Additional examples of useful peptides include, but are not limited to, bombesin, substance P, vasopressin, alpha-globulins, transferrin, fibrinogen, beta-lipoproteins, beta-globulins, prothrombin, ceruloplasmin, alpha₂-glycoproteins, alpha₂-globulins, fetuin, alpha₁-lipoproteins, alpha₁-globulins, albumin, prealbumin, and other bioactive proteins and recombinant protein products.